

REMARKS

In the official action of October 25, 2005, the Examiner has accepted the evidence of unexpected results previously submitted by applicants, but has contended that this evidence only supports the allowance of claim 2. The Examiner thus contends that this evidence is not commensurate in scope with claim 1, which is therefore once again rejected.

Although applicants strongly disagree with the Examiner's position in this regard, in order to expedite the prosecution of this application, claim 1 has now been amended to include the limitations of prior claim 2, while claim 2 and claims 17-22 have now been canceled. Claim 1 has also been slightly amended to be directed to the compound 7 α -methyl-19-nortestosterone and its pharmaceutically acceptable salts. This minor amendment is fully supported by the specification, such as the sentence bridging pages 7 and 8 thereof, and it is certainly clear that the evidence accepted by the Examiner is fully sufficient not only to support the subject matter of prior claim 2, but to also include this compound's pharmaceutically acceptable salts. One of ordinary skill in this art would thus immediately recognize that this claim is fully supported by this specification and the data referred to by the Examiner.

It is therefore clear that all of the claims now set forth in this application are in condition for allowance, and such action is respectfully solicited. However, applicants' amendments and cancellation of claims are not intended to in any way constitute a waiver of applicants' right to pursue these claims in additional applications.

Claims 1 and 3-22 have been rejected as being unpatentable over Bardin et al. in view of Reed et al. under 35 U.S.C. § 1039a). Bardin is said to disclose methods of

delivering various androgens such as non-5 α -reducible androgens, including the 7 α derivatives of androgens, and is said to claim delivery of such compounds transdermally in amounts of from 5 to 10 μ g/kg of body weight. Reed is said to show that such androgens as described in Bardin may be prepared in any form of transdermal delivery system in the form of emulsions, gels, aerosols, creams or lotions, and even patches, which is said to be articulated in various U.S. patents, referring to the abstract at page 7, lines 5-25. Reed is thus said to exemplify various androgens, and recites 7 α derivatives of androgens as suitable candidates for drug delivery systems at page 11, lines 10-19. The Examiner thus concludes that it would be obvious to prepare the 7 α derivatives of the androgens of Bardin in a transdermal delivery system as described by Reed and optimize suitable concentrations of the androgen by routine experimentation, as is said to be suggested by Bardin itself. One of ordinary skill in this art is said to have a reasonable expectation of success in making a transdermal formulation of Bardin's androgens because such compounds are expected to provide clinical benefits when administered transdermally. Claim 2 is allowed based on the evidence of unexpected results provided by applicants.

In view of applicants' amendments to claim 1, and the cancellation of claims 2 and 17-22, it is clear that this rejection is now moot, and that claim 1 is now in condition for allowance. Such action is therefore respectfully solicited. Once again, while applicants dispute the Examiner's position with respect to claims such as prior claim 1, as well as the impact of the declaration previously submitted, the amendment to claim 1 clearly obviates this rejection, leaving applicants the

option to pursue broader claims, if desired, in a separate application.

If for any reason the Examiner does not believe that this application is in condition for immediate allowance, it is respectfully requested that the Examiner telephone applicants' attorney at (908) 654-5000 in order to overcome any further such objection which the Examiner might have.

Finally, if there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: January 25, 2006

Respectfully submitted,

By 

Arnold H. Krumholz

Registration No.: 25,428

LERNER, DAVID, LITTENBERG,

KRUMHOLZ & MENTLIK, LLP

600 South Avenue West

Westfield, New Jersey 07090

(908) 654-5000

Attorney for Applicant